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A NATIONAL STRATEGY FOR DIGITAL HEALTH

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Executive Summary

COVID-19 was our wake-up call. Our world was turned upside down in an instant as health officials, government leaders, and everyone scrambled to deal with a disease that we had no way to treat and no way to cure. However, as they have in every crisis that has ever faced this nation, the American people rose to the challenge.

Now that the end of this global nightmare is just over the horizon, we cannot and must not slow down. We have seen first-hand how vulnerable we are. We have seen the need to be able to instantly scale healthcare services. We have seen the vital role that digital technology has played in saving lives, and it is our responsibility to make sure the lessons we have learned inspire us to climb even higher. We must do this, not only to prepare for the next global health emergency, but to improve the health and well-being of our people every day.

With proper leadership, 2021 can become a significant inflection point in our nation's health and public health history. The decisions that will be made in the coming months and years could set us on course to finally eliminate the tragic health disparities that were exacerbated by COVID-19. We now have the technology necessary to make sure every resident has the information they need to make the right choices for their health and the health of their families. We have the ability to instantaneously share data and evidenced-based treatments around the world. To seize this moment, we must have a national strategy for digital health that identifies a set of national priorities and guides the government and industry toward common goals.

If we let this opportunity pass, we risk worsening disparities in health by creating solutions that are only available to the privileged few.

National Strategy for Digital Health: Strategic Goals

Defining a national strategy for digital health is critical to ensure digital technologies are not just “layered” on top of the current system that is costly, inequitable for many, and often yields poor health outcomes. Federal agencies and other stakeholders are making significant investments in new tools, methods for capturing, providing, and using data, and innovative ways to provide health services. Yet, there is not agreement on a national set of priorities to guide this multitude of innovators toward common goals and priority outcomes. As a starting point, we put forward the following six strategic goals for revolutionizing the way we ensure the health and well-being of our citizens. The strategy is grounded in the following principles:

1. Empower the individual.
2. Every community, every person is important.
3. Collaborate and connect.
4. The end is improved health and well-being.
5. The system must learn and adapt.
6. Ensure privacy, security, and accountability.
7. Be bold.

These principles were used to guide development of a strategic framework, comprising six broad goals. Each goal is supported by recommended objectives describing actions for realizing a given goal.

Goal 1: Access, affordability, and utilization of universal broadband for everyone. As the COVID-19 pandemic powerfully illustrated, digital technologies are now foundational for obtaining health services, support, and information. We must not only provide equitable access to affordable broadband, but we must also ensure individuals can use it for health-related needs as well as opportunities in education, employment, social networks, the global economy, and nearly every other facet of modern life.

Goal 2: A sustainable health workforce that is prepared to use new technologies to deliver person-centered, integrated quality care. Digital technologies will impact traditional approaches to health occupations, tasks, and functions. Ultimately, a national digital health strategy requires a trained, sufficient workforce to meet the demand, and changes in organizational cultures that lead to a team-based approach to care and the shifting “the locus of care” to empowerment of the family and home.

Goal 3: Digital technologies empower individuals to safely and securely manage their health and well-being. Digital devices and systems are needed for collecting and using data to enable coordinated, holistic, and integrated care. They must equip individuals and providers with meaningful information and enable greater engagement of individuals in their health and wellness. Foundational to meeting this goal is ensuring individuals own their data and possess sufficient digital health literacy to use it. Building on that foundation, we need to grow our collective understanding of our personal health data, better utilizing the digitally enabled approaches to care, and ensuring they result in improved quality and outcomes while reducing costs.

Goal 4: Data exchange architectures, application interfaces, and standards that put data, information, and education into the hands of those who need it, when they need it, reliably and securely. Data is the epicenter of the digital health ecosystem. There must be timely, reliable, and appropriate access, exchange, and integration of that data for various types of users: patients, clinicians, service providers, researchers, policy makers, government programs, and technology developers. This interoperability will drive information-based decisions, enhance health services, and reshape how value is defined.

Goal 5: A digital health ecosystem that delivers timely access to information to inform public health decision-making and action. It is necessary to build a digital health information ecosystem that facilitates timely and complete bidirectional data flow throughout the federated public health ecosystem, in which constitutional authority to carry out public health functions lies with state health agencies, designated larger local public health departments, tribal nations, territories, and freely associated states. This transformation will use digital technologies and data to support a responsive, resilient public health system that facilitates timely bidirectional flow of the right information among diverse stakeholders to support evidence-based decision-making.

Goal 6: Integrated governance designed for the challenges of a digital health ecosystem. Widespread reform of existing fragmented and out-of-date governance structures is necessary to actualize the benefits of digital health and to support smart and strategic investments, avoid duplication, and harmonize efforts. Industry requires comprehensive policies that (1) address data protection, privacy, information security, patient rights, and transparency; (2) establish

protocols and standards to ensure interoperability and alignment of quality measures; and (3) ensure our national health security. This reform must be a holistic approach across all levels of government and encompass all stakeholders, to include health services providers, technology providers, hospitals, other primary care centers, patients, and other citizens, all of which must contribute to the development of digital health governance.

DRAFT

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Purpose

Digital health is the convergence of health-related sciences and digital technologies that empowers people and populations to manage their health and well-being. [1] A digital health ecosystem is driven by rapid, reliable, and secure flow of data to support team-based decision-making for both individual health and well-being and public health.

This strategy exists to describe national priorities for building such an ecosystem, one that will leverage digital technologies to transform the nation's experience with health and health care. The strategy is designed for leaders—in government, healthcare, public health, academia, health Information Technology (IT), and community-based organizations—who want to be involved in making that transformation happen. In some cases digital health has opened up new, promising frontiers and shown the promise of more equitable care for underrepresented and vulnerable populations such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. [2]

Overall Strategic Environment

Ensuring the health and well-being of our nation has long been challenging. The current system is costly and inequitable for many who need care, often overly burdensome for the providers of care, inefficient and sluggish for addressing public health needs, and yields surprisingly poor health outcomes for many. American health spending will reach nearly \$5 trillion, or 20 percent of gross domestic product by 2021, and annual per capita health expenditures in the United States are the highest in the world (USD \$11,172, on average, in 2018) [3]. The United States spends more on healthcare as a share of the economy—nearly twice as much as other high-income countries—yet has the lowest life expectancy and highest suicide rates. The United States also has the highest chronic disease burden and obesity rate among other high-income countries. More than one-quarter of adults report they have been diagnosed with two or more chronic conditions such as asthma, diabetes, and heart disease [4]. The current healthcare system is unsustainable.

In the face of this reality, there are concerted efforts to reform our current system. That system is built around treating illness, via a series of service transactions between a patient and their provider. There has been some progress toward a vision centered on the individual that is holistic both in terms of what influences health and how best to manage it. We have developed alternative measures of “quality” and models of how to pay for it. We have invested in making more data available, more rapidly, and more seamlessly. And we are beginning—just beginning—to recognize and account for the importance of social determinants of health (SDOH) of individuals and communities.

“Leveraging digital technologies to transform care delivery to reimagine the future health system that reaches out to connect with individuals and populations meaningfully is the promise of digital health.”

—HIMSS, Framework for Digital Health (2020)

Digital tools, technologies, and services hold the promise of enabling the kinds of changes sought. The availability of personal computers, smartphones, and two-way video conferencing technology has

allowed users in rural areas to have a clinical video visit with a remote provider. Asynchronous devices such as fitness monitors, remote monitoring devices, and wearable technology provide users insight to their own personal health and allow care teams to monitor treatment without requiring an office visit. Other developments, such as artificial intelligence (AI), genomics, predictive modeling, synthetic patients, and big data analytics, promise transformation of our data and information. Digital health capabilities are redefining the delivery of healthcare, management of public health, and our understanding of health itself. The bright future may be one in which market forces bring costs down, information flows to decision-support widgets on our wrists, and sensors provide a continuously updated picture of individual and public wellness.

Actually, one could argue that, as William Gibson famously noted, “The future is already here, it’s just not very evenly distributed.” Our experience with the COVID-19 pandemic suggests as much. It showed both the potential and potential risks associated with the kind of transformation that is underway with digital health. As in-patient healthcare services closed or reduced intake, remote services took their place. Little is known as yet about the quality of individual care under those circumstances. What is known is that the health impacts of the pandemic were experienced quite unevenly, with the negative impact borne disproportionately by people of color and those with lower incomes. Also, the sets of systems for detecting and responding to what became a pandemic were shown to be vulnerable. It seems clear that more data can and should be available for use across various stakeholders—the individual, care providers, public health professionals, community-based organizations, and researchers. We now need to give attention to major considerations that may have been given lower priority during the pandemic, such as how to take advantage of the data while ensuring ethical use, managing security, and protecting individual rights.

“The current transformation of healthcare must be more than just the adoption and integration of digital technology with existing healthcare.”

The current transformation of healthcare must be more than just the adoption and integration of digital technology with existing healthcare. To be successful, it must be a seismic shift in how we ensure the health and well-being of our citizens. The transformation is social, cognitive, and political, with the end goal participatory health—a partnership with digital devices collecting data and generating insights with new models of addressing the health and well-being of our nation.

With the proper leadership and strategy, 2021 can become a significant inflection point in our nation’s health and public health history. The decisions that will be made in the coming months and years could set us on course to finally eliminate the tragic health disparities that were exacerbated by COVID-19. We now have the technology necessary to make sure every resident has the information they need to make the right choices for their health and the health of their families. We have the ability to instantaneously share data and evidenced-based treatments around the world. To seize this moment, we must have a national strategy for digital health that identifies a set of national priorities and guides the government and industry toward common goals.

Vision

A transformed health ecosystem that leverages digital technologies to improve health and well-being for everyone.

Guiding Principles

The following principles guide development of this strategy:

1. **Empower the individual.** A transformed ecosystem will position the individual to take charge of their own health rather than being a passive recipient of transactional services. The individual should be empowered, protected, and a partner in care that is respectful of, and responsive to, their preferences, needs, and values.
2. **Every community, every person is important.** Ensure the strategy to transform the health ecosystem reduces, not exacerbates, current social inequalities in health, intentionally or unintentionally, accounts for SDOH, and advances health for all populations and communities including Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender and queer (LGBTQ+); persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. [5]
3. **Collaborate and connect.** The quality and degree of change called for requires that we all work together, across the boundaries of our distinct ecosystems and our diverging interests. The ecosystems must be connected, stakeholders must collaborate, and transparency must be a priority. These imperatives inform our understanding of how large-scale change—such as the shift to digital health—will occur and can be managed while maintaining stakeholder trust.
4. **The end is improved health and well-being.** National success in health can and should be measured in outcomes. Value resides in achieving positive outcomes—individual and public—while balancing attention to other key considerations, including cost, patient experience, and provider experience.
5. **The system must learn and adapt.** Data must be analyzed rapidly and effectively to yield actionable knowledge that transforms the health experience of all stakeholders, informs initiatives to reduce cost, and supports a flexible, sustainable ecosystem.
6. **Ensure privacy, security, and accountability.** Ensuring the privacy and security of individual information is critical to the development of a trusted digital health ecosystem.
7. **Be bold.** The health ecosystem is vital to the success of the nation, with the potential to greatly strengthen—or compromise—our security and economic development. Digital transformation is happening, and prompt, decisive, strategic action is needed to ensure the resulting ecosystem is robust, efficient, and equitable.

Strategic Goals

The strategy is structured by a set of six broad goals. For each goal, a number of objectives describe recommended actions that leaders may consider for achieving the goals.

Goal 1: Access, affordability, and utilization of universal broadband for everyone. As the COVID-19 pandemic powerfully illustrated, digital technologies are now foundational for obtaining health services, support, and information. We must not only provide equitable access to affordable broadband, but we must also ensure individuals can use it for health-related needs as well as opportunities in education, employment, social networks, the global economy, and nearly every other facet of modern life.

Goal 2: A sustainable health workforce that is prepared to use new technologies to deliver person-centered, integrated quality care. Digital technologies will impact traditional approaches to

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health occupations, tasks, and functions. Ultimately, a national digital health strategy requires a trained, sufficient workforce to meet the demand, and changes in organizational cultures that lead to a team-based approach to care and shifting “the locus of care” to empowerment of the family and home.

Goal 3: Digital technologies empower individuals to safely and securely manage their health and well-being. Digital devices and systems are needed for collecting and using data to enable coordinated, holistic, and integrated care. They must equip individuals and providers with meaningful information and enable greater engagement of individuals in their health and wellness. Foundational to meeting this goal is ensuring that individuals own their data and possess sufficient digital health literacy to use it. Building on that foundation, we need to grow our collective understanding of our personal health data, better utilizing the digitally enabled approaches to care, and ensuring they result in improved quality and outcomes while reducing costs.

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Goal 6: Integrated governance designed to meet the challenges of a digital health ecosystem. Widespread reform of existing fragmented and out-of-date governance structures is necessary to actualize the benefits of digital health and to support smart and strategic investments, avoid duplication, and harmonize efforts. Industry requires comprehensive policies that (1) address data protection, privacy, information security, patient rights, and transparency; (2) establish protocols and standards to ensure interoperability and alignment of quality measures; and (3) ensure our national health security. This reform must be a holistic approach across all levels of government and encompass all stakeholders to include health services providers, technology providers, hospitals, other primary care centers, patients, and other citizens, all of which must contribute to the development of digital health governance.

1. Goal 1. Access, affordability, and utilization of universal broadband for everyone.

As the COVID-19 pandemic powerfully illustrated, digital technologies are now foundational for obtaining health services, support, and information. We must not only provide equitable access to affordable broadband, but we must also ensure individuals can use it for health-related needs as well as opportunities in education, employment, social networks, the global economy, and nearly every other facet of modern life.

“[T]ens of millions of Americans do not have access to or cannot afford quality internet service.”

Brookings Institute, 5 Steps to get the internet to all Americans (2020)

Current and Future State

The coronavirus pandemic has fundamentally changed the way we work, learn, stay connected to family and friends, and seek healthcare. It also has magnified the gap between individuals who do and do not have access to technology devices, high-speed internet (broadband),¹ and the digital literacy to use the tools.

While the “digital divide” has existed in the United States for decades, bridging the digital divide is a critical component to the success of our public and veteran health, education, and economic well-being. Some have even argued that broadband access should be a “human right” because without it, other human rights such as the right to work and to basic education cannot be adequately realized [6]. Whether a human right or not, broadband is the modern infrastructure need of our country to connect communities to each other and to opportunities, in much the same way that the electric grid, interstate highway, and railroad systems were key infrastructure needs in the past to unify the nation and usher it into prosperity.

Great variation exists in access to broadband across states and disparities in access by income, race/ethnicity, rurality, disability status, age, and veteran status.

- **Income.** Higher-income Americans (64 percent) are more likely to have access to broadband and have multiple devices that enable them to go online than lower-income families (18 percent) [7].
- **Race/Ethnicity.** Whites are more likely than Blacks or Hispanics to report having broadband connection at home, while mobile devices are more likely to be used by Black and Hispanic people for online access options [8].
- **Geography.** While both urban and rural areas may lack broadband, urban regions are more likely than rural or mountainous zones to have access to 4G or fiber optic internet [9].
- **Disability.** Persons with disabilities have approximately half the rate of internet access compared to people without a disability [10], [11].

¹ The Federal Communications Commission (FCC) is the agency responsible for defining broadband. The metric they set forms the basis of determining whether the government can say that a household has access to broadband internet. Today, that metric is 25 megabits per second download (25 Mbps) and three megabits per second (3 Mbps) upload.

- **Age.** More than one in three U.S. households headed by a person age 65 or older do not have a desktop or a laptop computer, and more than half do not have a smartphone [12].
- **Veterans.** A substantial number of veterans suffer from a disability, reside in rural areas, or are older than the general population. These demographic factors combined result in many of the veteran population having lower rates of access to and adoption of broadband services [13].

As part of President Biden’s plan to build back better, he has committed to “expand broadband, or wireless broadband via 5G, to every American” [14]. Just like electricity, broadband has become an essential utility and must be available and affordable to everyone by 2025.

In addition, Congress recently took steps to empower the Federal Communications Commission (FCC) to take immediate actions to address the digital divide. Congress charged the FCC to develop a new \$3.2 billion program to help people pay for internet service during the pandemic. Congress also provided an additional \$249.95 million to allow the FCC to continue to expand connected care throughout the country and help more patients seek healthcare safely. Finally, the FCC is also committed to improving its broadband maps. Congress has appropriated \$65 million to help the agency develop better data for improved maps.

The United States has made great strides to improve infrastructure and connect communities in the past. In the late 1800s we built a transcontinental railroad that connected and unified the nation, reduced time and cost of travel, opened up markets to farmers, revolutionized commerce and other industries, and undergirded the industrial revolution. In the 1930s, we connected Americans to electricity and forever revolutionized our lives, improved education, created new markets, and brought industry to Middle America. In the 1950s we connected the nation's communities with the interstate highway system and thereby gave new freedoms to families, enabled economic mobility, and catalyzed new industries, from automotive to manufacturing. We can take the knowledge of our success in these past large public works and put them to use to ensure the availability and adoption of broadband ecosystems by everyone in the United States.

By 2025, we must achieve:

- **Broadband Access.** Establish the infrastructure to provide broadband access for all. Assuring all populations can affordably access infrastructure is fundamental to assure digital equity. Lack of proper internet infrastructure can contribute to poor or no internet connection. Cost of infrastructure continues to impede full adoption, so development and investment in large-scale cost-effective solutions that meet the needs of rural and other environments must continue.
- **Broadband Adoption.** Increase affordability of both access to broadband and the tools needed to use the internet. Some populations continue to experience challenges in accessing the internet because of high costs. While costs have decreased over time, the cost of technology, including smartphones and laptop computers, continues to challenge those who are financially vulnerable. Reducing the cost of connectivity and technology will help reduce the digital divide.
- **Broadband Utilization and Innovation.** Empower and engage communities in shaping their digital futures. Giving communities the tools and opportunities for shaping their own broadband ecosystems (e.g., technologies, software) will allow development of relevant applications, without requiring socialization and education. Certain individuals continue to face challenges in understanding and fully utilizing technology. Because our health, education, economic, and other sectors have become dependent on computers for access, barriers to their

use broadens the digital divide, or ‘participation inequality.’ All populations need to learn about the benefits and value and build trust in utilizing the internet to help achieve economic and social growth and participation. Better tools that are culturally and linguistically appropriate to meet the needs of diverse populations are also required. Assurances of privacy, trust, and data security must also be provided.

The future of individual and population health and well-being requires availability, accessibility, adoption, and utilization of the broadband ecosystem by the entire U.S. population. If we do not take steps to assure this vision, we will likely broaden rather than narrow health disparities.

Objectives

Several steps must be taken to ensure everyone has available, accessible broadband and the tools for adoption and utilization. Many of the steps need to be conducted concurrently.

1.1. Objective 1-1. Create a National Broadband Plan. (Timeframe: 1 year)

The last Plan (Connecting America: The National Broadband Plan) was developed in 2010 after Congress directed the FCC to develop a National Broadband Plan to provide every American “access to broadband capability” [15]. Given the critical reliance of communities on broadband in trying to access opportunity and the reliance of most industries on connectivity in trying to achieve prosperity, we need a new plan that:

- Considers the expanding needs and widening disparities of our communities while also considering significant technological advancements over the past decade (from network advancements such as 5G deployment and SpaceX’s construction of the Starlink broadband internet system, to reliance of almost all aspects of life on the internet during the COVID-19 pandemic).
- Supports “access to broadband capability,” as well as adoption, trust, and participation of every community.
- Includes broadband capability as part of a larger plan to develop “smart” communities in which technology is used to improve governance, planning, management, and livability by gathering and using real-world, real-time data [16].

1.2. Objective 1-2. Create accurate mapping of broadband availability and speed. (Timeframe: 1 year)

Government broadband data is provided by internet service providers (ISPs) with a vested interest in overstating broadband availability. Inaccurate maps hurt communities. For example, incorrect FCC maps may show communities as ineligible for funding for which they may in fact be eligible (an example grant program for which applicants can be impacted with incorrect speed information is U.S. Department of Agriculture’s [USDA] Community Connect Grant program [see “What is an eligible area?” section at: <https://www.rd.usda.gov/newsroom/news-release/usda-offers-community-connect-broadband-funding-applications-due-dec-23>]).

- There must be timely collection of detailed data.

- There must be development of more accurate maps about broadband availability by the Broadband Data Task Force that includes speed test data, specific information from ISPs on what homes they serve, affordability, and adoption information.
- Census blocks should no longer be the smallest geographic area used by the Census Bureau to determine access.

1.3. Objective 1-3. Create a government-wide approach to broadband adoption and affordability. (Timeframe: 4-6 years)

The current approach to broadband infrastructure is fragmented across the government and sometimes not aligned. For example, no coordination occurs amongst the various agencies on broadband and related programs on eligibility. As a result, what is considered rural for FCC does not necessarily align with USDA designations.

1.4. Objective 1-4. Redefine the definition of high-speed broadband. (Timeframe: 3 years)

The current definition of high-speed internet was set by the FCC in 2015 at 25 Mbps down/3MBPS up as the minimum standards for broadband. This outdated standard cannot actually handle 21st century needs—including the ability to meet with our health providers via videoconferences as well as to work and study at home. A standard of 100/100 megabits per second should be the minimum.

1.5. Objective 1-5. Assure equity and inclusivity in the design of all digital tools by engaging community members—especially from historically disadvantaged communities, including persons with disabilities—in a broadband-needs assessment and proposed interventions. (Timeframe: 2 years)

- Design digital tools and services with equity and inclusivity of access for all ages, abilities, and education levels, and engage all specific user groups, including minorities, persons with disabilities, elderly, and other vulnerable populations in the design, planning, implementation, and evaluation of digital health design and implementation.
- Ensure standards-based development and design of digital tools, to ensure accessibility to all populations in their healthcare settings.

1.6. Objective 1-6. Improve measurement, monitoring, research, and practice in digital health to account for health inequalities and varying levels of digital access. (Timeframe: 2 years)

To improve measurement, monitoring, research, and practice in digital health, we must first collect and analyze data on who lacks connectivity and to what degree, to help inform equitable resource distribution.

2. Goal 2. A sustainable health workforce that is prepared to use new technologies to deliver person-centered, integrated, and quality care.

Digital technologies will impact traditional approaches to health occupations, tasks, and functions. Ultimately, a national digital health strategy requires a sufficient and trained workforce to achieve improved outcomes in a team-based approach to care that shifts “the locus of care” to empowerment of the family. “Workforce” in this strategy is taken to encompass clinical and technical disciplines, as well as managers leading clinical care, public health, software development, and data science professionals. In addition, digital health creates an opportunity to provide much needed training and tracking of metrics for care providers that are learning how to best create experiences for underserved populations and track new types of data like sexual orientation and gender identity (SOGI) data.

Current and Future State

The digital transformation of health and public health systems is underway. The delivery of health education and health services will be driven by increasingly advanced technologies. From electronic health records (EHRs) to mobile technology, the Internet of Things, and virtual reality, to decision-making supercomputers, technology is a part of the current healthcare delivery landscape and will be a part of improving the health and well-being of individuals and populations in the future. However, the current workforce is not fully prepared on using technology and big data to improve outcomes. Studies on the many health workforce disciplines report 30-70 percent lack adequate skills to use digital technology and fully engage with digital information. [17, 18]

“A country’s ability to cultivate a digitally capable health workforce is one of the most important enabling factors underpinning national success in digital health.”

-Dr. Alfred Winter, Professor, Institute of Medical Informatics, Statistics, and Epidemiology of the University of Leipzig, Germany

The health workforce is comprised of a diverse set of occupations and industries. Currently, the supply for all types of health workers in the United States—physicians, nurses, allied health professionals, community outreach workers, and the multidisciplinary workforce of public health—has been outpaced by the demand, and it is expected to worsen with an aging population, increasing numbers of people with chronic disease, and large numbers of retirements.

As digital technologies continue to be integrated into healthcare delivery, the mix of skills required changes. Digital literacy and continuous education of health professionals in the knowledge, use, and application of digital technologies and data are mandatory elements of a digital health strategy. Without a workforce with the necessary skills, we will not be able to realize the full potential of digital innovations. In fact, technology may get in the way of work, having unintended consequences leading to burnout and early retirement [19]. Several barriers to technology integration within the existing workforce include:

- Resistance to new ways of working

- Very limited funding opportunities for existing public health staff to take advantage of academic or fellowship training programs in informatics or data science
- Absences of technology from existing core and discipline-specific competencies

Looking ahead, we know it takes time and effort to learn how to employ new technologies. The capacity and competency of the health workforce cannot be created in a matter of months but must start immediately, focusing on both a pipeline of skilled health professionals as well as upskilling the current health workforce.

Higher education institutions and professional associations must lead the transformation of the health workforce, updating and expanding the curricula to include discipline-relevant digital health skills and competencies. This can be started by building on the Workforce Development Workgroup of the EU*U.S. eHealth Work Project that developed a digital health competency framework to inform required changes in the education of health workers [20]. For public health, applied informatics competencies must be integrated into all public health training programs. Certification programs for public health informaticians must be developed to ensure a base level of expertise for those filling informatics roles in governmental health agencies.

Additionally, the knowledge and skills of informal caregivers and teachers and trainers should be addressed as well as the availability, quality, and quantity of courses, programs, and training material at various levels for various professions. Attention should be given to adapt job descriptions, provide on-the-job training and staff development and address the acceptance, trust, and useability of the technologies [21].

Incentives and opportunities to upskill the current workforce should be considered, comparable to the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act. It funded two distinct health IT workforce training programs: University-Based Training Program and Community College Consortia Program, which supported training of more than 20,000 working professionals and students between 2010 and 2013 [22].

Finally, professional and ethical frameworks must be updated. The health workforce must trust the technology, particularly when there are real impacts to clinical outcomes. In addition, the ethical and legal issues of the digital health technology and use of data, including issues of liability and intellectual property, must be addressed.

Objectives

2.1. Objective 2-1. Invest in upskilling current members of the health workforce. (Timeframe: 2-4 years)

Prioritizing the upskilling of the current workforce is seen as critically important now as we develop strategies for creating a pipeline of and hiring new employees with the right skills to work in the era of digital health. Incentives and opportunities to upskill the current workforce should be considered.

- Incentives should be provided by the federal government across the broad spectrum of the health workforce to embrace new technology, as was done through the 2009 HITECH Act.
- For the public health workforce, investment is needed in funded training opportunities for existing governmental public health agencies to increase workforce competencies in

informatics and data science. Health sector employers and organizations are also responsible for providing their workforce with the necessary skills and fostering buy-in.

2.2. Objective 2-2. Modernize post-secondary accreditation requirements for the health workforce, to include digital literacy and skill development. (Estimated timeframe: 6+ years)

Modernizing post-secondary accreditation requirements must include:

- Engaging with professional associations and accrediting bodies (Association of American Medical Colleges, Association of Schools and Programs of Public Health, Council on Education for Public Health, Commission on Collegiate Nursing Education, Accreditation Commission for Education in Nursing, Accrediting Commission of Career Schools and Colleges) to evaluate existing curricula and identify gaps in digital health.
- Developing discipline-specific and appropriate, knowledge, skills, and abilities in digital health.
- Incorporating new knowledge, skills, abilities into health workforce curriculum.

2.3. Objective 2-3. Leverage governmental funding streams for professional training and degree programs aimed at digital literacy skill development. (Estimated timeframe: 4-6 years)

Leveraging governmental funding streams for professional training and degree programs includes:

- Expanding existing and creating sustaining federal funding streams for professional training and degree programs aimed at digital literacy and skill development.
- Establishing funding targets for federal and state programs.

2.4. Objective 2-4. Expand recruitment and enrollment in health workforce academic programs from diverse backgrounds to address capacity needs. (Estimated timeframe: 4-6 years)

To ensure a diverse workforce, recruitment and enrollment must be expanded by:

- Recruitment and enrollment of diverse people including Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender and queer (LGBTQ+); persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.
- Establishing discipline-specific capacity needs for the health workforce.
- Creating metrics for understanding the number of people aware of and seeking employment in health data science and informatics.
- Creating model incentive programs for training commitments for work in rural and under-resourced areas.

2.5. Objective 2-5. Support model programming for continuing education in digital health and data science, to prepare the health workforce with necessary skills. (Estimated timeframe: 4-6 years)

All efforts to support model programming for continuing education should be inclusive of learning needs for intra- and interdisciplinary training in clinical and public health informatics, software development, and data science, to build team-based practice. These efforts include:

- Support discipline-specific assessments of the health workforce with respect to digital health knowledge, skills, and abilities.
- Engage professional associations, licensing, and accrediting bodies to create a compendium of model continuing education programs to address gaps in knowledge, skills, and abilities.
- Promote these programs through health workforce organizations as well as organizations devoted to digital health, such as Healthcare Information and Management Systems Society (HIMSS) and the American Telemedicine Society.
- Support certificate programs and micro-credentialing opportunities for upskilling the current health workforce.
- Explore opportunities with existing academic schools and programs of public health and Massive Open Online Courses like Coursera.
- Support options for increasing access of existing digital health and telehealth certificate programs like those supported by American Board of Telehealth and American Telemedicine Association.

2.6. Objective 2-6. Integrate health informaticians and data scientists into the health workforce to strengthen capacity to support a digitally capable health workforce. (Estimated timeframe: 4-6 years)

To integrate health informaticians and data scientists into the health workforce, efforts must be made to:

- Create employment vehicles for data scientists and informaticians for traditionally under-resourced healthcare and public health organizations.
- Create scholarship and loan forgiveness programs to make these organizations attractive employment opportunities, while addressing much needed capacity.
- Provide direct federal and state grants for public health organizations to foster this expertise in their organizations.
- Create new, nontraditional pathways to increase participation of underserved communities into the health workforce, inclusive of computer scientists as well as traditional health workforce.
- Support apprenticeships and internship models of training. Include a broad range of skills, including software coding and data science.

2.7. Objective 2-7. Foster opportunities for leadership development in digital health disciplines. (Estimated timeframe: 4-6 years)

To foster opportunities for leadership development, a strategy needs to be developed with professional organizations, such as HIMSS and American Medical Informatics Association to identify or, as needed, create programs for developing leadership skills tailored to digital health. As digital health evolves, leaders can expect to experience employee and professional pushback as digital competencies are required, clinician roles change, and there is lack of appropriate organization and system-wide digital health strategy. Pushback may also come where there is a lack of expertise or experience in digital leadership, there is rigid organizational structures and policy settings, or where traditional funding models are used that are not equipped to manage health in a digital society (Rowlands, 2019).

2.8. Objective 2-8. Develop opportunities for early exposure to concepts of digital health in K-12 education for all socioeconomic groups. (Estimated timeframe: 6+ years)

To increase early exposure to the variety of career opportunities in the health workforce as well as increasing the base knowledge of health and digital health for consumers, include digital health literacy, computer coding, STEM education, and access to technology for K-12 education Objective 2-8. Create opportunities for the development of creative digital health solutions for traditionally underserved communities. Create opportunities by providing communities with digital health tools so they can create new solutions to serve their communities' needs. This could include communities with disabilities (e.g., blindness, hearing loss) as well as geographic communities (e.g., Appalachian region) and those in traditionally underserved work groups (e.g., migrant workers).

3. Goal 3. Digital technologies empower individuals to safely and securely manage their health and well-being.

Digital devices and systems are needed for collecting and using data to enable coordinated, holistic, and integrated care. They must equip individuals and providers with meaningful information and enable greater engagement of individuals in their health and wellness. Foundational to meeting this goal is ensuring that individuals own their data and possess sufficient digital health literacy to use it. Building on that foundation, we need to grow our collective understanding of our personal health data, better utilizing the digitally-enabled approaches to care and ensuring they result in improved quality and outcomes while reducing costs.

Current and Future State

The availability of virtual care and digital health technologies has been growing slowly over time; however, utilization and adoption was limited. The availability and affordability of personal computers, smartphones, and two-way video conferencing technology allowed users in rural areas to have a clinical video visit with a remote provider. There has been considerable growth in wearable technology such as personal fitness monitors, as well as remote health monitoring devices, which provide users insight to their own personal health and allow care teams to monitor patients and adjust treatment without requiring an office visit. These synchronous and asynchronous digital health capabilities are redefining the delivery of healthcare. The recent COVID-19 pandemic thrust virtual health into the forefront as in-patient healthcare services closed or reduced intake. As the nation slowly emerges from the COVID-19 pandemic, evidence suggests that digital health services are becoming a standard means in the delivery of care.

Discussion of the current and future state of person-centered health can be organized into several areas, which become the focus of strategic action:

- **Data Ownership.** The idea of who owns personal health data, and who profits from it, has entered the national dialogue through a combination of publicized instances of misuse of personal data, new federal regulations, and increasing recognition of the value and usefulness of instantly available information. Personal health data is lucrative, and a vast number and type of entities have access to and profit from it. Individuals often seem to be the least able to aggregate, control, use, and even access their health data themselves, with actual data ownership unachievable under most state law. Recently, Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC) programs and rules have strengthened support for individuals to have access to their data. Truly empowering the individual in the future would entail extending beyond access to changes needed for individuals to have more control of their information.
- **Digital Health Literacy.** Giving individuals control of their data is important for equity and health impacts. Access to tools (e.g., handheld personal devices) for both capturing and managing that data, and access to internet-based resources is also critical. However, an additional factor influencing the equitable impacts of digital health is the “ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem” [23]. This is digital health literacy, as defined by the World Health Organization (WHO). As with other facets of health and healthcare in this country, digital health literacy is marked by significant disparities, with negative implications for health of underserved populations. To shape a future state with a more equitable, digitally literate population will require action on multiple fronts, such as investing in tools that address the needs of underserved populations, tracking the access and usage of digital health resources, and exposing individuals—patients and others—to training in the nature and use of new technologies [24].
- **Patient Experience.** Digital health technology has been widely used during the COVID-19 pandemic, and patients have come to expect streamlined communication, care coordination, and quality care, both in person and via telemedicine. But some of the tools are very complicated and difficult to use, so the current technology platforms have room for improvement. In the future, digital health tools will allow patients to schedule appointments, review clinical notes, hold video appointments, and communicate with providers and care teams. Apps designed along the lines of Open Table for appointments and Uber for medical transportation will bring convenience to the health context that consumers have to come to expect elsewhere.
- **Provider Experience.** Healthcare delivery is attempting to transition from a volume-based model (fee-for-service) to a model focused on value driven by the Quadruple aim goals: better patient experiences, health outcomes, reduced costs, and better provider experiences. Care teams and providers are optimistic that digital health technology and remote patient monitoring (RPM) devices will significantly impact patient outcomes. Digital health will allow providers to have near-real-time access to patient health data, improve provider efficiency, improve communications with patients, and improve provider-to-provider communication for knowledge sharing. However, care teams and providers are cautious and concerned that the amount of health data will overwhelm their staff and will not be reimbursed properly. Also,

cultural factors persist that make the integration of digital health technologies to standard workflows uneven.

- **Reimbursement.** The traditional model for reimbursement of healthcare services is the fee-for-service payment model where providers are reimbursed for each service rendered. While this model is simple and straightforward in terms of what services can be billed and reimbursed, the model does not consider a person's overall health nor patient outcomes. Digital technologies hold promise for increasing efficiency and coordination and achieving desirable health outcomes. However, the lack of reimbursement for digital health services has long impeded greater adoption. As a result of the COVID-19 pandemic, many temporary reforms and waivers were established that allowed virtual care to flourish; however, many inequities remain in reimbursement for virtual care versus traditional in-person care. Resolving those inequities is key to future success, as is analysis of the impact that tools for clinical decision support (CDS), patient engagement, point of care, and consumer access have on outcomes. Measuring those impacts is essential to show the value of digital health and to influence reimbursement models. There is a growing shift toward a value-based care model. In value-based care, healthcare providers are reimbursed based on patient outcomes, to include reducing chronic care conditions. Value-based care incentivizes providers to focus on preventive care, education, and improved health outcomes.
- **Cost.** Virtual health may lower costs for many reasons, such as reduced travel, less time away from work for the patient, and generally improved efficiency. However, the net cost associated with implementation of digital health—and therefore the overall return on investment—is not yet well understood. The costs for development, integration, training, operations, and maintenance comprise an important part of the overall picture, as well as any costs associated with expansion of visits that may be driven by use of telehealth. Moreover, it is not at all clear how the overall digital health market will evolve. The cost of implementing digital health may be controlled through competition as users purchase more sophisticated personal RPM devices/wearables and as healthcare organizations integrate digital health into their core processes and practices. Methods and data are needed for building this full understanding of the economics and net costs.
- **Safety/Security.** Digital health technologies, including virtual visits and wearable devices, provide a convenient and cost-effective way to empower individuals to manage their own health and allow care teams to monitor treatment remotely. However, many challenges must be addressed to enable person-centered care via digital health technologies. First, most digital health technologies utilize third-party external services that may expose the user and health organization to security and privacy risks. Care must be taken to ensure virtual visits maintain patient privacy, and RPM devices collect and transmit personal health data to a care team via third-party platforms. Second, there is an uneven distribution of trust and confidence in digital technologies, devices, and their generated data. Providers trust digital health data being generated by certified medical devices such as an implantable cardiac monitor and pacemaker—devices typically approved by the Food and Drug Administration (FDA). However, personal commercial wearables—which have seen enormous growth—are generally identified as “educational” and are not considered trustworthy. Finally, availability of liability protection regarding digital health data is uneven and can be a challenge for some providers. This is likely due in part to the incomplete understanding of how such data, particularly from remote devices, can be affected by other influences and lifestyle, such as exercise and stress.

To achieve widespread use of digital health, all necessary privacy and security controls must be in place to ensure digital health technology and RPM devices remain secure and cannot harm the user. RPM devices must be isolated within the user's home environment and the provider able to assure end-to-end data security between the patient and the health delivery organization. The potential liability is a concern that will have to be addressed through governance. Trust and confidence in the new and emerging forms of digital health will grow when care teams and providers have more information about the tradeoffs associated with different care delivery approaches, structures are in place to govern liability, and care teams have the tools and technology for data provenance.

- **Precision Medicine.** Precision medicine, also called precision health, is revolutionizing how we improve health and treat disease. Its goal is to empower healthcare providers to tailor treatment and prevention strategies to individuals' unique characteristics. Examples include targeted medicines for disease and preventative approaches to address individual co-morbidities and medical pre-dispositions. In the public health space, advances in genomics and other technologies helped improve the efficacy and speed of identifying the COVID virus and its variants and mapping their spread. Key research programs such as the Department of Veteran Affairs Million Veterans Program and the National Institutes of Health (NIH) All of Us Research Program are creating repositories of genetic, clinical, lifestyle, military exposure, and other data. Precision medicine will require continued innovations and development of scalable solutions for collection, storage, processing, exchanging, and curating the massive volumes of data. It will also require the education, encouragement, and recruitment of highly trained professionals across a broad range of healthcare, technical, legal, regulatory, and business fields. Success will further depend on expanding knowledge of genomics to a much broader audience, to include those at the front lines of care. Long-term, widely available care will require expert genetic counseling and collaborative patient-provider, evidence-based treatment decisions.

Objectives

3.1. Objective 3-1. Institute policy and legal changes necessary to give individuals ownership of their health data. (Timeframe: 3 years)

CMS and ONC have acted to broaden individuals' access to their data. Those developments are crucial to fully empowering the individual. Achieving ownership by individuals will require legislative action, and implementation will entail identification, consideration, and resolution of many issues for patient data control, including maintaining the security of health data as demand and disbursement of that data increases across users. We need strong patient data privacy, use policies, and innovative approaches to data governance. And we need policies, standards, and data processing techniques in place that will enable sharing of individual-level data during national public health emergencies.

3.2. Objective 3-2. Create a national action plan to improve digital health literacy. (Estimated Timeframe: 1 year)

Ownership of and access to one's data are important features of an effective digital health ecosystem. But the individual will truly benefit only to the extent that they have sufficient digital health literacy to understand how to use the data coming to them—along with fully understanding their rights as a consumer of such data. Similar to the National Action Plan to Improve Health Literacy developed in 2010, we now need a new plan for health and digital health literacy [25]. The plan should serve as a

foundation for engaging organizations, professionals, policy makers, consumers, individuals, and families in a multisector effort to identify and address the needs for health and digital health literacy.

- The plan should be used to provide needed supports and services that equip and empower the population with needed digital skills and health literacy.
- Support implementation of the plan by publishing a guide on improving digital health literacy and trust for all, regardless of demographics such as income or geography, as part of a comprehensive implementation strategy across the United States.

3.3. Objective 3-3. Invest in growing methods and data to understand the impacts of digital health approaches. (Timeframe: 1-3 years)

Perform analysis to understand the impact of telemedicine and other digital health technologies on access to care and health outcomes. The COVID-19 pandemic has resulted in a transformation of the healthcare delivery system, and this analysis will help decision makers and the healthcare organizations understand the growth of digital health and virtual care, the quality of care, and patient and provider engagement before and during the COVID-19 pandemic.

- Conduct an evaluation of the use of digital health technologies. This should include and identify which stakeholders/populations have adopted digital health, how they have used these technologies, along with which stakeholders/populations have not adopted digital health technologies and what barriers these populations have encountered.
- As more data becomes available, invest in research to quantify improved quality and outcomes. Coordinate across federal agencies, states, and others to develop an approach and identify resources for a collaborative cost/benefit analysis of digital health impacts.
- Invest in patient-engagement tools to help ensure value-based care, including helping to find solutions addressing medication adherence, chronic diseases, and promoting overall patient wellness.
- Monitor costs to determine what policy levers would help and where targeted investments make sense. As the unit cost for technology continues to drop, we should see a corresponding decrease in the cost of implementing digital health tools, both for consumers and organizations. However, as utilization increases there may not be a decline in overall costs to the entire healthcare system.

3.4. Objective 3-4. Develop a framework for reasonable use of digital health. (Timeframe: 1-3 years)

Implement a framework to allow the healthcare industry to adjust their delivery of care models to integrate virtual care with traditional in-person care. Virtual care/digital health will not totally replace traditional in-person care in the foreseeable future. The “Reasonable Use” template will identify the appropriate mix of in-person and virtual care, based on best practices for optimal utilization and high-quality care.

- This framework will create a standard template for common, high-volume diagnoses and procedures, along with measure parameters of the relative mix of virtual health and face-to-face encounter types.

- Establish best practices for the use of digital health services to ensure optimal utilization and high-quality care and quantify the quality gaps and cost variation with and without the use of virtual health. These standards will be applied to each clinical practice to define when digital health is appropriate for optimal care, which will result in better health outcomes and reduced cost. Consider how evidence-based practice must adapt for digital health. Conventional methods may not be applicable or as useful.
- Leverage ongoing efforts of quality organizations to assess if virtual care/digital health can provide the same or better level of quality as traditional in-person care at a similar or lower cost.

3.5. Objective 3-5. Specify a glide path for transition to reimbursement for digital modalities. (Timeframe: 3-5 years)

Identifying a path for transitions to reimbursement for digital modalities includes:

- Developing data-driven models of the effect of reimbursement changes on access, quality, and cost within fee-for-service and value-based care delivery and payment models for digital modalities.
- For digital services already reimbursed (e.g., video visits within states with payment parity), explore the impact of different approaches for transitioning payment to value-based care models.
- For digital services not always reimbursed (e.g., video visits within states without payment parity), examine the impact of introducing payment on access, quality, and cost.

3.6. Objective 3-6. Analyze and address restrictions on use of telemedicine. (Timeframe: 1-3 years)

For synchronous delivery of care via telemedicine, state licensure statutes and other requirements such as state scope of practice laws and facility privileging processes can inhibit care delivery and increase costs, especially for rural providers. In general, providers must have a license from the state of the originating (patient) site and must additionally conform to the scope-of-practice for that state. Health facilities are required to review their providers' qualifications before approving them for institutional privileges. To inform policymakers and other stakeholders on these issues:

- Explore the effectiveness of licensure compacts agreed upon by state licensing boards, in terms of cost, quality, and access impacts to provide data to guide future approaches.
- Analyze changes in cross-state licensure, scope of practice, and emergency privileging approaches during the COVID-19 pandemic, to understand the impact on cost, quality, and access to provide data to guide future approaches.

3.7. Objective 3-7. Develop components that will further mature the nation's precision medicine capability. (Timeframe: 4-7 years)

- Invest in high-processing computing, databases, and storage to aid the DNA sequencing process and to correlate genetic sequences with disease profiles and that support the use of other bioinformatics tools. (Timeframe 2-3 years)

- Develop high-speed networks and interfaces to support the vast volume of data that must be transferred and made accessible to geographically distributed collaborating researchers and clinicians, industry, academia, laboratories, pharmaceutical, and healthcare environments. (Timeframe 3-5 years)
- Advance security standards, regulations, processes, and technologies to ensure appropriate privacy and anonymity—the lack of which would hamper participation. (Timeframe 4-7 years)
- Support programs aimed at growing genomics literacy of care providers and individuals. (Timeframe 3-5 years)

4. Goal 4. Data exchange architectures, application interfaces, and standards that put data, information, and education into the hands of those who need it, when they need it, reliably and securely.

Health interoperability is an enabler of individual access and ownership of health data, with data rights that are fair and equitable. It enables clinicians to coordinate care among institutions and act based on comprehensive and current information. It allows for robust observational data studies, leveraging access to a significantly higher percentage of patients' data than typically volunteer for clinical trials. This ensures representation from previously underrepresented study subjects, providing insights and results that could rival the gold standard randomized controlled trial. Health interoperability allows for safe, responsible, and transparent public health reporting and monitoring. Interoperability supercharges the “Learning Health System” where advances in scientific and medical literature to the point of care in months, week, or days rather than the reported 17-year lag time we currently experience [26]. Health interoperability enables deep systemic data-driven analysis of the healthcare system, allowing policymakers and administrators to eliminate fraud, waste, and abuse and cut costs, using process improvement to increase efficiency, all while increasing individual access to care and improving healthcare quality. Finally, health interoperability enables innovation in the health IT space: new tools and services that take advantage of interoperable data and services, including the application of AI and machine learning (ML).

Current and Future State

Historically there has been strong bipartisan support for health interoperability, as demonstrated by the passing of the 21st Century Cures Act, and currently several federal agencies are conducting operations in the area of health interoperability. However, special interests and their financial and economic incentives have inhibited the adoption of interoperable solutions.

Health interoperability has been slowly gaining traction in private industry. The financial and economic incentives for health interoperability have not been large enough to compel private industry to adopt solutions and technologies. The ability to lock in customers to solutions and platforms, while maintaining a stranglehold on data (the new oil in the Information Age), far outweighs the economic benefits that private corporations would gain from interoperability, even though the societal benefits far outweigh the advantages for private industry.

Impetus for interoperability improvements has been provided by U.S. government payment incentives for the reporting of Electronic Clinical Quality Measures (eCQMs) by EHR systems and U.S.

government regulations requiring the adoption of Application Programming Interfaces (APIs) using consensus-based standards to provide access to patient data. Additional pressure has come from value-based programs that provide incentives for coordinated care and penalties for readmissions and other poor outcomes that result from siloed approaches to care and data management and ownership [27].

There remains, however, a long way to go. The COVID-19 pandemic has demonstrated the critical need for federated data. Widespread deployment of end-to-end solutions is low, and therefore widespread adoption at scale by patients, consumers, and platforms is low, and therefore societal value (benefits less the cost of care) is not yet realized.

Change is feasible in a number of areas that would fundamentally advance interoperability:

- **Data capture at the point of care.** Data capture methods vary widely, with terminology standards and non-standard collection processes. Progress will be defined by widespread use of controlled vocabularies and terminologies, standard common-sense language terminologies free of proprietary licensing, and standard units of measure.
- **National Patient Identifier (NPI).** While provider organizations and clinicians have unique national identifiers, patients do not. This leads to medical errors, missing data, and an error-prone ability to match patient data across systems. Issuing a unique NPI should be possible, given the nation's experience with other identification records such as Social Security numbers and driver's licenses. Including an NPI will ensure patient records can be reliably discovered, matched, and merged.
- **Patient data privacy, use, and innovative governance.** Patient data is the gold or oil of the health IT economy, so the financial incentive is to control it and limit access, which is complex and varied by jurisdiction. New Hampshire is the only U.S. state that declares that patients own their own data. In nearly all cases, the data is housed in proprietary databases or consolidated in cloud databases secured and tightly controlled by the vendors (who likely claim ownership of the data as well). The United States must adopt national patient data ownership laws, which would flip the financial and economic incentives of the industry toward interoperability and financial success based on population health rather than stockpiling and financial success based on data ownership. One benefit will be enhanced transparency of the cost of care, increasing the power of individuals and their families to manage health.
- **API.** Data discovery and access depend on APIs. Current U.S. regulations require support for HL7 (Health Level 7) Fast Healthcare Interoperability Resources (FHIR) only for the Patient Data Access use case. Many other use cases remain unsupported, especially those needed for healthcare reimbursement. Other limitations keep consumer adoption low. Future success of the digital health system will be indicated by reliable discovery and access of a full range of data via APIs. This will include data related to genomics, medical or wearable devices, benefit design, claims and coverage, appointment and scheduling, and SDOH.
- **Metrics Standardization.** There must be evolution of metrics, from the status quo limited standardization in the definition and reporting of cohorts and metrics, to standardization that includes eCQM definitions, reports, population health and public health queries, patient cohorts used in the context of CDS and research, complex target/objective/thresholds for public and private programs, social programs, and the measurement of access, quality, and efficiency.
- **Algorithms.** The accessibility of algorithms is highly constrained, such that they are often non-transferable and expensive to obtain. Meaningful interoperability will include easy access and

transfer of standardized algorithms, increasingly via open source and, as appropriate, available for public inspection.

- **Effective Clinical Practice.** With the current, relatively limited state of interoperability, health services will be standardized in a single health system, at best. A key feature of the future digital health system will be rapid dissemination of learning and best practices, and open-source comparative effectiveness and cost-effectiveness research that allows patients and their families to make informed care choices.

Objectives

4.1. Objective 4-1. Standardize the data. (Timeframe: NPI 4-6 years; Patient Data Ownership laws 1-3 years; HL7 FHIR U.S. Core transition 1-2 years. United States Core Data for Interoperability continues to expand with new data elements annually. Payer Use Cases: 4-6 years. Other Use Cases: 7+ years)

Health interoperability requires the rigorous employment and adoption of consensus-based standards for data representation and clinical and financial meaning with standard units of measure. No scientific endeavor in history is testable or repeatable without standardized data—what and how observational data is being recorded. Health interoperability and the subsequent use cases are no exception.

- Create and adopt an NPI. Issuing a unique NPI will ensure patient data can be reliably discovered, matched, and merged across settings. This is crucial to reduce medical errors and facilitate the exchange and matching of patient data. [28].
 - Stakeholders: Patients, ONC (Standards), CMS (claims), Health IT vendors.
 - Incentives: Reduction of costs and harm related to medical errors. Reduction of complex processes currently in use to mitigate the patient matching issues.
- Adopt national patient data ownership laws at the federal level. When patients own their health data and have rights and control over the use of that data, the financial and economic incentives of the industry flip toward interoperability and financial success based on population health rather than stockpiling and financial success based on data ownership. (See Objective 3-1)
 - Stakeholders: Patients.
 - Incentives: Reversal of economic incentives that have inhibited interoperability.
- Transition completely to a standard set of open terminologies and eliminate local or proprietary terminologies (e.g., CPT-4) unless a nationwide license is provided at the federal level (e.g., RxNorm is open, ICD-10-CM and ICD-10-PCS is licensed nationwide by National Center for Health Statistics, Logical Observation Identifiers Names and Codes licensed by the National Library of Medicine, Medicare Severity Diagnosis Related Groups is published by CMS, Systematized Nomenclature of Medicine [SNOMED] is licensed by SNOMED International).
 - Engage stakeholders from terminology standards organizations, ONC (patient data), CMS (patient and payer data and claims), NIH (standards licensing), Health IT vendors.
 - Payment for terminology development is provided in an explicit and transparent manner by public sources.

- Continue funding and development for emerging data elements. The United States has begun to standardize data with the ONC's United States Core Data for Interoperability (USCDI). This is a core data set, but funding and development must continue for emerging data elements (e.g., in USCDI, the Level 2, Level 1, and DRAFT data elements).
 - Engage patients, clinicians, ONC, CMS, Veterans Health Administration (VHA), Centers for Disease Control and Prevention's (CDC), Health IT vendors, payers.

4.2. Objective 4-2. Standardize the APIs. (Timeframe: Patient Data Access through HL7 FHIR U.S. Core Implementation Guide - 2 years; Payer Use Cases - 4 to 6 years; Other use cases - TBD)

Health interoperability requires that the data is discoverable and accessible when it is needed. Achieving this at scale requires adoption of consensus-based standards for data query and exchange. Currently, this means APIs. These APIs should align with FAIR Data Principles (Findable, Accessible, Interoperable, Reusable) and utilize security best practices. APIs should facilitate connections between patients, providers, and payers or new Integrated Delivery Systems that combine care delivery and risk management.

- Transition the national public and private health infrastructure to a common open API stack for all health use cases—throughout patient, provider, payer, public health, and other services. The logical front-runner is HL7 FHIR. Additional funding and development must continue to develop scenarios that are ongoing (e.g., Prior Authorization and Provider Directory) and those that are unaddressed or unfinished (e.g., Price Transparency, Patient Data Ownership and Data Use Agreements, Medical Devices).
- Research is also needed to ensure patient responses to these changes lead to improved outcomes rather than avoidance of care due to complexity of information. Industry has demonstrated reluctance to interoperate in the absence of regulation or as a requirement for reimbursement (e.g., through CMS Medicare claims or private payer use of publicly promulgated payment standards).
- Engage with standards organizations, patients, providers, payers, ONC, CMS, VHA, CDC, Agency for Healthcare Research and Quality (AHRQ), Health IT vendors.

4.3. Objective 4-3. Standardize the metrics. (Timeframe: Full migration, 4-6 years)

After standardizing data and APIs, the next step is to standardize how we ask questions or measure problems. Metrics should be designed both at a system level (e.g., mortality rate of a surgical procedure or total cost of care for a procedure) and patient level (e.g., mortality rate of patients like me in my area or patient out-of-pocket costs or cost to a particular payer). This often translates to one or more data elements being captured or observed (potentially even novel data elements), but metrics are at a higher level than data: what are we measuring and why? This can take the form of one or more complex queries.

- Transition the quality/performance measurement and public health reporting to dynamic queries composed of Clinical Quality Language (CQL), HL7 FHIR, and the standardized data elements. Once these core infrastructure elements are in place, the burden of annual eCQM definitions will be drastically reduced (e.g., write CQL once, run everywhere)

without modifications) as well as traditional public health reporting and emerging public health threats (e.g., new dynamic queries based on emerging knowledge of novel pandemics).

- Engage with CMS, CDC, Health Resources & Services Administration (HRSA), Health IT vendors, measure developers and receivers, clinical registries, public health agencies.
- Establish Key Performance Indicators for the health system to include access, costs, and quality—measure them using the standardized data and APIs—and report them transparently.
- Stakeholders will be Department of Health and Human Services (HHS), U.S. population, clinicians/healthcare systems, quality organizations like The Joint Commission, and payers.

4.4. Objective 4-4. Standardize the algorithms. (Timeframe: partially completed, but overall, this is a long-term effort, 6+ years)

Today's health algorithms are expensive, proprietary, and often highly localized (e.g., deployed at a single location). CDS systems, eCQM calculators, eligibility and prior-authorization algorithms, claims processing decisions, and AI and ML models are often non-transferrable due to the state of the foundational layers (i.e., data, API, metrics) not being standardized or the underlying measures being owned by a specific organization. Once the previous layers are standardized, the design, development, testing, innovation, and proliferation of open algorithms can flourish and spread rapidly.

- Transition CDS artifacts to CQL. Continue funding the AHRQ CDS Connect platform, for example, and open new lines of funding to contract the development of open CDS algorithms and AI/ML research by leading academic medical centers and other stakeholders. The development of the public infrastructure of standardized clinical algorithms requires significant investment.
- Enhance consistency in standards in algorithm development. AI and ML have great promise, but they also pose significant risks. The underlying data must be accurate, complete, free from bias, and not otherwise flawed. There also must be standards for ensuring the privacy and the security of the data. Recommendations or guidelines for the editorial and curation components of data governance can help ensure that ML and AI algorithms are rooted in curated data and free from bias. Without standards and guidance, health disparities can be increased, and poor decisions could be made that have dire consequences. There is a risk of becoming more efficient in transmitting misinformation in the evolving digital world, and there is a need to get ahead of this and outline editorial and curation practices in digital health to ensure quality data and information.
- Stakeholders include patients, clinicians, payers, CMS, AHRQ, Health IT vendors.

5. Goal 5. A digital health ecosystem that delivers timely access to information to inform public health decision-making and action.

It is necessary to build a digital health information ecosystem that facilitates timely and complete bidirectional data flow throughout the federated public health ecosystem, in which constitutional authority to carry out public health functions lies with state health agencies, designated larger local

public health departments, tribal nations, territories, and freely associated states. This transformation will use digital technologies and data to support a responsive, resilient public health system that facilitates timely bidirectional flow of the right information among diverse stakeholders to promote preparedness and support real-time, evidence-based decision-making.

Current and Future State

Data reporting of public health events typically flows from local public health departments to state and then federal public health agencies. Assistance provided by federal agencies occurs at the invitation of state and local public health agencies.

The federated nature of public health governance and program implementation leads to many challenges to achieving timely and complete data exchange used to facilitate public health decision-making and action. These challenges span a wide range of diverse workforce and technical capabilities and standards implementation across the country and even within states, and differences in how standards are used and applied.

Although the United States spends more than \$3 trillion on healthcare annually, less than three percent of that is directed to public health functions, and that proportion has declined since 2000 [29]. Adjusting for inflation, the CDC budget—from which the more than 3,000 state, tribal, local, or territorial (STLT) public health agencies receive approximately 75 percent of their funding—remained almost unchanged since 2008 [30]. As a result, many federal and STLT public health departments lack the resources to maintain or upgrade their informatics infrastructure to leverage new technologies and analytic techniques [31]. Further, Congressional appropriation of funds to HHS agencies (e.g., CDC, HRSA) does not take a systems approach; rather, it provides project- or condition-specific funding. In 2018, CDC reported that it had more than 100 different surveillance systems and programs receiving data from STLT jurisdictions [32], and that does not include separate reporting to other federal public health agencies (e.g., HRSA) that also fund public health activities. Funding is inequitably distributed among jurisdictions, ranging from \$69.25 per person in Alaska to \$18.44 per person in New Jersey [33]. This inequity results in differential technical and informatics capacity for public health surveillance, preparedness, and response across our country [34]. It also presents challenges for recruitment and retention of highly skilled IT staff, data scientists, and informaticists to support public health agencies' use of their data in new and innovative ways. Further complicating the issue and impacting jurisdictions' ability to recruit and retain staff is the fact that public health funding typically surges during and immediately after a public health emergency and then quickly disappears, forcing public health agencies and departments to rely on hiring temporary staff or laying them off when the funding disappears.

Similarly, the federated approach results in differences in how standards are adopted and used across public health jurisdictions. For example, states maintain individual immunization information systems that leverage HL7 Version 2 (V2) messaging. Many jurisdictions interpreted the HL7 V2 guidance differently. Also, regulatory reporting requirements (what conditions must be reported, when, and with what information) vary across jurisdictions [35]. This leads to significant burdens on health IT developers to accommodate jurisdiction-specific customizations for condition identification within EHRs and standard messages to accommodate reporting requirements and facilitate information sharing across jurisdictions. Moreover, much of the data needed to support public health activities is inadequately captured in EHRs or may be stored in other systems or by other sectors (e.g., community-based organizations) that are not connected electronically to public health agencies. Data sharing across jurisdictions, with federal partners, and across health-related settings and sectors, is further

complicated by a lack of understanding by reporters and potential data-sharing partners of the regulatory scope of public health reporting and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) [36], and inconsistent data governance rules and data-sharing agreements.

It is necessary to advance the digital public health ecosystem, acknowledging the challenges of a federated public health system dependent on other health-related sectors for data. In this future state, funding for public health is based on an integrated systems approach that leverages whole-of-government, industry, and academia alliances and focuses on population health outcomes [37] while supporting both technology and data-science innovation and system maintenance and upgrades. Public health STLT staff will be trained so they can be informed and active participants in the standards-development process and the data-science communities, allowing all 3,000+ jurisdictions to leverage the best innovations and data-interoperability practices for rapid and comprehensive public health preparedness and response. Data sharing for public health action will leverage and reuse existing standards in a systematic and cohesive way that eliminates jurisdiction-specific customizations and facilitates easier data sharing in support across health-related sectors, jurisdictions, and government.

Governance opportunities around public health data sharing will be implemented that streamline privacy-focused data sharing and use [38]. Health-related sectors will be educated on the new governance strategies, to ensure fostering of best practices during data-sharing activities.

And fundamental to all these transitions, public health will leverage new technologies and innovation to adhere to its core goal of monitoring the health and well-being of all members of the community—whether digitally enabled or not—to ensure everyone is moving toward a healthier and safer state of being.

Objectives

5.1. Objective 5-1. Develop enduring funding strategies that encourage a systems approach to public health technology solution development. (Timeframe: 1-3 years)

This long-term objective focuses on modernizing how public health infrastructure is funded, to ensure a systems-level approach that leads to sustained support of modern technology. To achieve this long-term objective, the White House and Congress should in the next one to three years pivot to a new way of funding public health. This would include:

- Discontinuation of line-item, condition-, or project-specific funding for public health agencies.
- Funding exploration of whether expansion, reuse, or redesign of existing systems is appropriate over building new, for new informatics projects.
- Provision of funding for long-term system maintenance and upgrades.

To promote this activity further, the White House may wish to consider transforming the CDC Director or other public health leader role into a cabinet-level position. This would ensure public health is directly represented in conversations about funding and the security of the U.S. population.

HHS agencies should promulgate funding to STLT health departments in the same systems-oriented way. Until funding mechanisms are corrected so they support a systems-level approach, the nation will continue to operate with siloed public health systems that do not leverage the best that technology has to offer.

In recognition that incentives encourage electronic information exchange between clinical organizations and public health entities [39] [40] [41] [42], we recommend that in the next one to three years the White House and Congress also incentivize clinical and public health entities to electronically bidirectionally exchange complete and timely information.

Advocacy groups for public health agencies and clinical organizations should work with Congress and the White House to implement these incentives.

5.2. Objective 5-2. Develop a national process and entity for governance of public health infrastructure investment that facilitates and reduces the burden of multi-jurisdictional and cross-sector data sharing for public health action. (Timeframe: 1-3 years)

We recognize a need for a multi-sector group like the Digital Bridge Initiative [43], which includes representatives from federal and STLT public health agencies and healthcare and health IT organizations. We recommend HHS establish a public-private partnership in the next one to three years. Representatives from clinical, health IT, and public health should be partnered with to:

- Recruit representatives from national entities (government agencies, scientific and professional associations, non-governmental organizations, corporations, etc.) to develop the public health informatics strategic plan.
- Create a governance body inclusive of representatives from healthcare, health IT, and public health.

The scope of the Digital Bridge Initiative itself could also feasibly be expanded because it includes the necessary representation; however, a sustainable funding model must exist to support this expanded scope. After the new entity is established it should quickly:

- Create a governance process to review and approve requests for use of non-standard data elements to support public health action of emerging conditions.
- Work with data partners to reduce variation in data-sharing agreements.

Creating a governance process to review and approve requests for use of non-standard data elements to support public health action of emerging conditions will help reduce variation in the implementation of standards across public health jurisdictions, which will streamline reporting burdens on healthcare and health IT organizations. The new governance body entity should consider novel ways to support these activities, such as a Turbo Tax-like tool that could be used to create data-sharing agreements to reduce variation. Ultimately, the new entity should position itself as an advocate that brings together representatives from the relevant sectors to ensure public health data needs are considered in all aspects of the digital health infrastructure and exchange conversation.

Finally, the governance process should ensure there is an appropriate balancing of public health needs under normal and extreme conditions. Systems are needed to maintain steady resourcing and response during normal public health operations; those same systems must also trigger and support “surge” responses during an emergency. Maintaining both levels of capability—while maintaining attention to access and equity—will require adjustments to the status quo for policy, process, and resourcing.

5.3. Objective 5-3. Ensure accessible and equitable availability and use of modern technology and standards for all public health jurisdictions. (Timeframe: 1-5 years)

Public health jurisdictions possess a wide array of technical capabilities and resources. To achieve a robust public health infrastructure within our digital health ecosystem, we must provide support to our most remote and least technologically advanced jurisdictions so they can participate in the new ecosystem. This means that in the next one to five years, HHS should partner with the newly formed entity, public health stakeholder organizations, and public health departments to:

- Develop shared services and support adoption among jurisdictions and public health providers.

Across these shared services, and among jurisdictions that may opt to leverage their own technology and standards, CDC should:

- Promote jurisdictional adoption of standards, current and innovative technology, and advanced analytics through funding incentives, requirements, and staff upskilling.

CDC may wish to emulate the ONC's Beacon Community program [44], which advanced health IT infrastructure and exchange within communities and developed innovative approaches. CDC could also offer funding to support peer-to-peer networks for collaboration, on-the-ground training, real-time advice, and sharing of lessons learned and best practices. Some of the infrastructure for these types of collaboration and training exists through organizations like the Council of State and Territorial Epidemiologists (CSTE), Association of State and Territorial Health Officials (ASTHO), and National Association of County and City Health Officials (NACCHO). These organizations would need a stable and sustainable source of funding to provide robust training to the more than 3,000 public health jurisdictions across the country.

The shared services could be added to Association of Public Health Laboratories Informatics Messaging Service (AIMS) [45] or a similar platform. The AIMS platform already hosts such services as the Reportable Conditions Knowledge Management System [46], a repository of public health reporting requirements to support electronic case reporting, and Sara Alert™ [47], an open-source tool that supports automated case and contact monitoring. If selected, the AIMS platform would need to be scaled and resourced to support new use cases.

Providing jurisdictions with access to services on a shared platform reduces the cost of implementation and maintenance and minimizes the need to staff IT or informatics experts to support those tools. It will be critical to remember that new digital tools will bring changes to workflows and processes, and staff will need to be trained. As a result, CDC should in the next one to three years support jurisdictions by:

- Facilitating recruitment and retention of data scientists, software engineers, informatics professionals, and IT experts at jurisdictional public health departments. These experts will allow STLT health departments to maximize the use of data flowing through the new digital ecosystem, through advanced analytics and innovation. Historically, public health jurisdictions are funded based on population rather than infrastructure need. This means rural health departments and under-resourced departments may lack the funds and staff to maintain or upgrade their infrastructure. To ensure equity in data sharing capabilities as technology advances, CDC should immediately equitably fund jurisdictions based on system upgrade and maintenance needs.

5.4. Objective 5-4. Maximize the use of existing standards when exchanging public health data, and actively integrate public health experts in the standards development, implementation, and maintenance processes. (Timeframe 1-3 years)

Through this objective, the nation will advance its ability to electronically exchange data and reduce barriers for that sharing across jurisdictions, settings, and sectors. In the next one to three years, CDC should:

- Equitably upskill jurisdictional public health staff to understand how to use standards and join and participate broadly on standards communities.
- Expand equitable representation of jurisdictional public health on standards committees, Connect-a-thons, and USCDI (not just the public health committees) to ensure appropriate representation of public health use cases and functional requirements, to support effective public health data exchange.
- Support dissemination of tools to public health agencies that support mapping across various standards.

These steps will ensure public health is informed and equipped to correctly leverage standards and participates in the conversations and development of new standards. CDC should partner with standards bodies like HL7 and with public health stakeholder organizations like CSTE, ASTHO, and NACCHO to operationalize and ensure offering of equitable representation and upskilling opportunities to all public health staff. In addition, Congress should fund a set of regional “Centers of Excellence” (similar to the USDA agricultural extension centers and ONC’s regional extension centers) to train public health staff and support ongoing education and outreach to engage those staff in standards development and use across the country.

In addition, the nation must ensure new standards work in the real world. To that end, CDC should:

- Ensure pilot testing of new standards in real-world clinical and public health environments before promoting widespread adoption.
- In the near-term and working with HL7, a FHIR Public Health Accelerator, and a CDC-led testing collaborative, CDC could partner with clinical and public health organizations to test new FHIR tools and implementation guides to ensure they account for the vagaries of real-world implementation. Recommendations for changes would flow from the testing collaborative to HL7 by way of the Accelerator to ensure the standards are implementable and ready for systematic widespread adoption.

Once the new entity described above is established, it should partner with public health and digital health stakeholders to develop a core set of foundational standards to support public health activities. A foundational set of standards should limit the variability in public health reporting standards that currently exists and ensure easier scalability for most new reporting mechanisms.

5.5. Objective 5-5. Improve access to and use of data to inform public health action by establishing new and enhancing existing relationships and streamlining data exchange processes. (Timeframe: 1-5 years)

This objective ensures STLT public health departments and their data partners are equipped with the right technology, people, and processes to bidirectionally share data (e.g., complete reporting to public health that includes relevant clinical and laboratory data, demographics [age, sex, race, ethnicity], SDOH, biometrics, other patient-generated data). This final Goal 5 objective focuses on ensuring data exchanged in support of public health action are the right data, are used to promote improved public and population health for all, and foster an environment of continued evolution and innovation. To achieve the latter, HHS should partner with other parts of the federal government, public health partners, industry, and academia to immediately:

- Develop a mechanism to continually scan and evaluate new data opportunities.
- Systematically measure the health and well-being of individuals not captured through digital mechanisms.
- Establish data exchange with non-traditional settings and sectors, including community-based programs services.
- Support timely and relevant knowledge transfer between public health and clinical and community partners through electronic tools such as CDS.

A current and very real barrier to data exchange between clinical and public health partners is a lack of understanding by many clinical staff on appropriate practices for sharing information for public health action. To combat this, HHS should work with academic institutions and physician associations over the next five years to:

- Incorporate education about appropriate data-sharing practices with public health agencies into accredited clinical training programs and continuing education.

HIPAA was created well before many technological advances. It is frequently misunderstood or misapplied to limit data sharing. It may be necessary to reexamine HIPAA in the context of privacy-preserving record linkage and other tools to promote secure data exchange in support of critical public health activities and health research. In the next one-three years, the White House should:

- Convene an independent entity to make recommendations on how to modernize HIPAA to promote more effective and efficient data exchange in support of public health preparedness and response.

A further challenge to data exchange with and among federal and STLT public health agencies is the lengthy onboarding process and multiple data pipelines organizations must connect with to share data. The entity established in Objective 5-2 should work immediately to reduce the number of different data transmission pipelines that must be created to send data from one location to another.

The AIMS platform, and CDC's content-based routing services, may be expanded or emulated to achieve this objective.

Currently, mandates exist in many states only for electronic laboratory reporting. Other forms of public health reporting (e.g., case-based surveillance or registry reporting) are typically not mandated. This results in poor adoption of those non-mandated services. Through advocacy and education by the entity established through Objective 5-2, state legislatures (or the appropriate government entity) should mandate electronic public health reporting at the appropriate jurisdictional level (e.g., state, tribe, territory).

These five public-health-oriented objectives focus on the challenges of a federated public health system. A digital ecosystem transformation is only possible if the fundamental components of the

public health infrastructure are addressed. By operationalizing these objectives, the United States should be on its way to a responsive, resilient public health system that facilitates timely bidirectional flow of the right information among diverse stakeholders to support real-time, evidence-based decision-making.

6. Goal 6. Integrated governance designed for the challenges of a digital health ecosystem.

Widespread reform of existing fragmented and out-of-date governance structures is necessary to actualize the benefits of digital health and to support smart and strategic investments, avoid duplication, and harmonize efforts. Industry requires comprehensive policies that (1) address data protection, privacy, information security, patient rights, and transparency; (2) establish protocols and standards to ensure interoperability and alignment of quality measures; and (3) ensure our national health security. This reform must be a holistic approach across all levels of government and encompass all stakeholders to include health services providers, technology providers, hospitals, other primary care centers, patients, and other citizens, all of which must contribute to the development of digital health governance.

Current and Future State

Digital technologies are increasingly prevalent in healthcare, and data produced from these technologies is used for decision-making, health management, and research. This data also provides information to care givers, health service providers, and patients.

Current governance of the digital health ecosystem and associated technologies is fractured, lacks clear roles and responsibilities for stewards of health data, and lacks defined mechanisms for enforcement of what minimal protections do exist. In addition, the current state of governance does not fully account for the breadth and types of data generated, nor consider the evolving technical infrastructure and disparate needs of diverse stakeholder groups, including consumers, that comprise the digital health ecosystem.

“Governance frameworks and solutions of current health systems are no longer effective or adequate for digital health systems of the future.”

HIMSS, Framework for Digital Health (2020)

Data privacy and security regulations offer some specific examples of this fragmented approach, with different agencies responsible for regulating different aspects of digital privacy and security, different industries that use and generate data, and different types of data creating gaps in oversight and confusion about how to interpret and apply the rules.

For example, separate federal privacy laws govern different areas of the U.S. healthcare system. Perhaps the most widely known example is HIPAA. HHS has enacted regulations that protect a category of medical information called “protected health information” (PHI). HIPAA generally applies to (1) using and sharing PHI, (2) disclosing information to consumers, (3) safeguarding and securing PHI, and (4) notifying consumers following a breach of PHI [48].

With respect to sharing information, HIPAA’s privacy regulations prohibit covered entities from using PHI or sharing it with third parties without patient consent, unless such information is being used or shared for treatment, payment, or “healthcare operations” purposes or unless another exception applies

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[49]. Regarding consumer disclosures, covered entities must provide individuals with “adequate notice of the uses and disclosures of PHI that may be made by the covered entity, and of the individual’s rights and the covered entities legal duties with respect to PHI.” Regarding data security, covered entities must maintain safeguards to prevent threats or hazards to the security of electronic PHI. The HIPAA regulations also contain a data-breach notification requirement, which requires that covered entities notify the affected individuals within 60 calendar days after discovering a breach of “unsecured” PHI. The increasing use of individual non-PHI data by healthcare entities necessitates development of additional regulatory guidance.

State laws add to the complexity of the regulatory framework governing data, particularly with regard to data breaches and the recognition that widespread collection of personal information can endanger individuals’ privacy and security. California enacted the first data-breach notification law in 2003. Since then, 48 states have passed laws requiring individuals to be notified if their information is compromised [50]. These laws contain different, and often incompatible, provisions about the type of information protected, the entities covered, and the definition of “breach.” Notification requirements also differ from state to state, which makes enforcement challenging. Further complicating the scenario is the Federal Trade Commission’s (FTC) general power to prohibit “unfair and deceptive trade practices,” through which the commission has attempted to establish a data-security baseline through more than 60 different enforcement actions (www.ftc.gov/enforcement/cases-proceedings/terms/245). The FTC also has a health data-breach notification rule, but it is reactive only and lacks meaningful consequences.

Recently, enactment of more comprehensive data protection laws at the state and international levels have further complicated the regulatory landscape by introducing differing standards. California legislators designed The California Consumer Privacy Act to protect the rights of individuals in California by allowing them to have access to and delete data that companies collect about them, regardless of the type of data or the custodian of that data [51]. In addition, it gives individuals the right to opt out of having their data sold. Similarly, the goal of the European Union’s (EU) General Data Protection Regulation [52] is to help make Europe “fit for the digital age” by (1) addressing the protection of natural persons regarding the processing of their personal data, (2) prescribing requirements for the free movement of that data, and (3) providing rules for companies and public bodies to ensure privacy and the appropriate handling of data.

Implications of this complex legal and regulatory landscape for the future of digital health will also be shaped by a number of factors, including:

- Lack of business models and processes that support self-management and ethical practices.
- Siloed health information systems and lack of interoperability and data standardization across digital platforms and technologies.
- Out-of-date funding models that do not account for healthcare provided in a digital society (e.g., telemedicine).
- Lack of a comprehensive legal framework that adequately reflects the complex intersection of sensitive data, electronic records, information security, system interoperability, patient rights, user responsibilities, contractual provisions and arrangements, and accepted risks.

A national strategy for digital health should have as its foundation a sustainable and robust governance structure, including a regulatory framework led by federal agencies in collaboration with the private sector, state, tribal, and local governments. A collaborative structure would ensure that policies and the

regulatory environment appropriately guard data privacy and security to support prudent data stewardship. It would also ensure accountability for data protection, while enabling secure data access and usage for patient and provider decisions, public safety, and public health purposes.

An effective governance structure must define foundational principles and competencies for trust, accountability, protection of data, and methods to leverage data analytics for health-based decisions for individuals, public needs, and research. It should enumerate and clearly define specific roles and responsibilities of each actor and allow for effective oversight.

Governance must account for the continuously evolving developments in communications and technology, particularly in the areas of social media and wearables. Governance further requires the simplification and consolidation of the existing regulatory structure addressing data privacy and security to clarify responsibilities and address gap areas.

Governance must address conventional data derived from the clinical context as well as emerging types of health data, including patient-generated health data (e.g., derived from wearables), data from medical devices, and data generated outside clinical settings.

Consumers, clinicians, and organizations using health data would benefit from a more comprehensive approach to data privacy regulation. Clearer guidelines that dictate when and how organizations must inform consumers about the use or transfer of their data, how that data should be handled and treated, and what should be done in the event of a data breach would foster consumer confidence in organizations using their data for healthcare purposes and would benefit clinicians by alleviating concerns regarding individual responsibility.

Some healthcare professionals perceive that existing regulatory policies and mechanisms impose too great a burden and do not account for how costs and claims will be reimbursed or how technologies will impact the patient and clinician relationship. Organizations using health data likely would not favor additional regulations initially. However, they may be persuaded that clarifying ambiguous regulations would ultimately facilitate decision-making, clarify business operations, reduce potential liability, and increase consumer confidence. More-comprehensive, less-ambiguous regulations would support organizations in implementing appropriate practices and compliance.

Objectives

6.1. Objective 6-1. Declare digital health a national priority. (Timeframe: 1 year)

The federal government must expressly and explicitly support the transformation of health systems in this country and the creation of a trusted digital health ecosystem. Declaring digital health as a national priority has high value. Such a declaration will align government and private-sector resource strategies and enable a comprehensive and transparent approach to funding. The declaration also becomes a tool for bridging the digital divide and disparities in access to healthcare, because citizens become aware of the government's prioritization of digital health. Lastly, a declaration means the government is making a commitment to its citizens, who in turn can demand results, whether directly through government actions or through their representatives.

6.2. Objective 6-2. Establish an entity to create a governance structure applicable across the digital health enterprise. (Timeframe 1-3 years)

A central entity should be responsible for creating and managing a comprehensive governance structure to promote coordination, efficiency, and consistency across the digital health enterprise. It would comprise representatives from government agencies including HHS and VHA, Department of Defense, and non-government stakeholders. Its responsibilities would include:

- Develop a task force or consortium to inform and coordinate efforts across the federal government, through a Federal Advisory Committee Act or White House Executive Office initiative.
- Capture and apply public and private-sector enterprise member feedback into a consistent and regular contribution to the governance process and advise on regulatory, legislative, and policy initiatives.
- Coordinate with private-sector professional and trade organizations to establish a Center of Excellence to identify best practices, regulatory recommendations, and ethical guidance and implement a governance structure.
- Engage stakeholders to define obstacles to the application of a trusted digital health ecosystem and identify health priorities and focus areas.
- Develop timelines and an implementation plan for a governance structure for the digital health ecosystem.

To ensure effective alignment and coordination across agencies, a central executive entity such as the Office of Science and Technology Policy should lead. This would generate the leadership and momentum required to get the strategic initiative established. Once there is momentum in place, day-to-day management could shift to a more operational entity. This would help ensure the initiative's sustainability through political changes.

6.3. Objective 6-3. Define explicit roles, responsibilities, and rights that promote accountability, ethical use of data, and appropriate protection of data. (Timeframe: 1-3 years)

- Convene stakeholder groups across the digital health ecosystems in both the public and private sector, to include but not be limited to government, private-sector organizations, private citizens.
- Develop and agree upon the roles, responsibilities, and rights of stakeholders within the health sector, including private citizens.
- Extend roles, responsibilities, and rights beyond the health sector to encompass web services, researchers, and other organizations.
- Ensure patients and caregivers actively provide input into the governance model and remain at the center of the governance conversation.
- Model a comprehensive governance culture that promotes equitable access to and delivery of quality, trusted, and affordable health services as well as data applications to support a holistic approach to healthcare.

6.4. Objective 6-4. Develop actionable guidelines that create a culture of respect and responsibility and that drive ethical stewardship of digital health. (Timeframe: 3-5 years)

Develop an evidence base to drive policies and standards regarding the use of digital technologies.

- The task force or consortium established in Objective 6-2 will establish consensus-based, comprehensive foundational principles that provide a strong, transparent, and inclusive governance process. Principles currently articulated in the “Ethical Framework for the Use of Consumer-Generated Data in Health Care”² could serve as a starting point for development and consensus.
- Leverage the consensus-based principles to write guidelines that drive actionable stewardship of digital health.
- Promote consistent use of consensus-based guidelines for safety, security, privacy, interoperability, and the ethical use of data within the ecosystem, which would include ethical use of health data in technologies such as AI, predictive modeling, and big data analytics, by supporting adoption and dissemination by regulatory, accreditation, association, and other governing bodies.
- Define and continuously refine through regular stakeholder and public input foundational concepts and competencies such as the digital health enterprise, trust, accountability, protection of data, and methods to leverage data analytics for health-based decisions for individuals, organizations, and public needs.

6.5. Objective 6-5. Provide assistance and information to support stakeholders in operationalizing guidelines. (Timeframe: 4-6 years)

- Establish a collaborative environment for policy and investment management discussions based on the Federal Data Strategy and built on the commonality stakeholder organizations.
- Establish ethical and business approaches, processes, practices for data sharing, data exchange, and analytics to enhance interoperability.
- Empower users of health data with education and transparency about the potential implications and consequences of data use, so they can make informed decisions about sharing, disclosing, using, and stewarding data.
- Establish collaborative structures to preserve, disseminate, and build upon institutional knowledge to improve accurate interpretation and ethical use of data.
- Articulate requirements for data sharing, quality and accuracy of health information, data ownership, ethical use, and public health needs.

6.6. Objective 6-6. Incrementally institutionalize governance structures into law. (Timeframe: 6+ years)

² “An Ethical Framework for the Use of Consumer Generated Data in Health Care: <https://www.mitre.org/publications/technical-papers/an-ethical-framework-for-the-use-of-consumer-generated-data-in-health>

- Align and harmonize governance structures at all levels—local, state, and national, as well as within tribal nations and territories, to reduce conflicting processes, guidance, and regulations and improve oversight functions, while being mindful of federalism issues and jurisdictional differences.
- Develop a coordinated federal/state policy framework to support use of digital technologies, agree on appropriate uses of health data, and articulate requirements for data sharing, quality and accuracy of health information, data ownership, ethical use of data, and use of data for public health needs.
- Work with Government Accountability Office and Office of Management and Budget to outline and identify legislative initiatives to further refine the federal government role in governance and oversight.
- Amend the current framework of HIPAA to protect privacy as individuals and providers embrace new data-driven tools to manage their health and well-being and deliver services and supports.
- Empower tribal, state, and federal agencies that use health data or interact with companies using health data to lead industry by example and adopt practices consistent with the guidelines and standards recommended by the entity tasked with creating the Governance Structure. Work with HHS, ONC, National Institute of Standards and Technology, FDA, FCC, FTC, and other government agencies to issue guidance to organizations that use health data to adopt practices consistent with guidelines and standards recommended by the entity tasked with creating the Governance Structure.
- Draft model legislation based on the guidelines and standards recommended by the entity tasked with creating the Governance Structure, to offer a consistent set of definitions, rules, and enforcement at the state, tribal, and local level.

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Acronyms

Term	Definition
AHRQ	Agency for Healthcare Research and Quality
AI	Artificial Intelligence
AIMS	Association of Public Health Laboratories Informatics Messaging Service
API	Application Programming Interfaces
ASTHO	Association of State and Territorial Health Officials
CDC	Center for Disease Control and Prevention
CDS	Clinical Decision Support
CMS	Centers for Medicare & Medicaid Services
CQL	Clinical Quality Language
CSTE	Council of State and Territorial Epidemiologists
eCQM	Electronic Clinical Quality Measures
EHR	electronic health records
EU	European Union
FAIR	Findable, Accessible, Interoperable, Reusable
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FTC	Federal Trade Commission
HHS	U.S. Department of Health and Human Services
HIMSS	Healthcare Information and Management Systems Society
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health
HL7	Health Level 7
HRSA	Health Resources & Services Administration
ISP	internet service provider
IT	information technology
ML	Machine Learning
NACCHO	National Association of County and City Health Officials
NIH	National Institutes of Health
NPI	National Patient Identifier
ONC	Office of the National Coordinator for Health Information Technology
PHI	protected health information

RPM	remote patient monitoring
SDOH	social determinants of health
SNOMED	Systematized Nomenclature of Medicine
STLT	state, tribal, local, or territorial
USCDI	United States Core Data for Interoperability
USDA	U.S. Department of Agriculture
V2	Version 2
VHA	Veterans Health Administration

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